

Supply Chain, Support Services and Protective Services

Non-Employee Visitation and Onboarding Standard Operating Procedure

Target Group:		Original Date of Issue:	Version
Cleveland Clinic US Locations		Not Cot	
Approved by: Date	Last	Not Set Prepared by:	2 Effective Date
Approved by. Date	Approved/Reviewed:	Prepared by.	Effective Date
Board of Directors- Main, BOG/MEC- Main, Gordon Snow, Stephen Downey	09/28/2023	Maria Angelica Carrino (PROJECT MANAGER III)	09/28/2023
Avon Hospital:		Euclid Hospital:	
MEC approval date: 2/15/2021		MEC approval date: 2/15/2021	
Board approval date: 3/17/2021		Board approval date: 3/17/2021	
Effective Date: 3/24/2021		Effective Date: 3/24/2021	
Estados Hospitals		1120	
Fairview Hospital:		Hillcrest Hospital:	
MEC approval date: 2/15/2021		MEC approval date: 2/15/2021	
Board approval date: 3/17/2021		Board approval date: 3/17/2021	
Effective Date: 3/24/2021		Effective Date: 3/24/2021	
Lutheran Hospital:		Marymount Hospital:	
MEC approval date: 2/15/2021		MEC approval date: 2/15/2021	
Board approval date: 3/17/2021		Board approval date: 3/17/2021	
Effective Date: 3/24/2021		Effective Date: 3/24/2021	
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Medina Hospital:		South Pointe Hospital:	
MEC approval date: 2/15/2021		MEC approval date: 2/15/2021	
Board approval date: 3/17/2021		Board approval date: 3/17/2021	
Effective Date: 3/24/2021		Effective Date: 3/24/2021	
CCCHR:		Weston, Florida:	
MEC approval date: 4/1/2022		MEC approval date: 4/26/2021	
Board approval date: 4/1/2022		Board approval date: 4/26/2021	
Effective Date: 4/1/2022		Effective Date: 4/26/2021	

Martin Health:

MEC approval date: 5/11/2021 Board approval date: 5/11/2021

Effective Date: 5/11/2021

Coral Springs, FL ASC/FHC:

MEC/CSOC approval date: 4/29/2021

Board approval date: 4/29/2021

Effective Date: 4/29/2021

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

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Purpose

This SOP establishes uniform guidelines and onboarding requirements for Supplier Representatives, including: non-employees, vendors, students, volunteers, contractors, construction workers, affiliated medical professionals, observers, etc., who require access to Cleveland Clinic (CC) networks or facilities including: Cleveland Clinic patient care areas (defined as any area that an individual will or may come into contact and/or in the same vicinity with patients of Cleveland Clinic such as hospitals, family health centers, ambulatory surgery centers, physician offices, etc.), administrative buildings, new construction sites, servers, applications, etc. Adherence to this SOP safeguards proper Supplier Representative vetting and orientation prior to assignment at Cleveland Clinic via a third party and ensures reasonable control and identification of Supplier Representatives to maintain a safe environment for our patients, caregivers, visitors, and infrastructure.

This standard operating procedure is applicable to all Cleveland Clinic health system locations and mandates a centralized system for housing compliance elements in Protective Services in the event of an audit.

Vendor Representatives can play an important role in patient care and the operation of Cleveland Clinic assets and are permitted to be present in Cleveland Clinic (CC) facilities or

have access to our network and applications at the request of an appropriate caregiver. To ensure safety for our patients and caregivers, Security Administrative Services maintains a standardized onboarding process for all Cleveland Clinic health system locations prior to assignment.

Definitions

Cleveland Clinic United States locations- Includes the main campus, Avon, Euclid, Fairview, Hillcrest, Lutheran, Marymount, Medina, South Pointe, Children's Hospital for Rehabilitation, Weston Hospital, Coral Springs Ambulatory Surgery Center, Martin North Hospital, Martin South Hospital, Tradition Hospital, and all Family Health Centers, Physician practice sites, Nevada practice sites, Emergency Departments, Express Care Centers, Urgent Care Centers and Ambulatory Surgical Centers reporting to these facilities.

Cleveland Clinic Personnel and Facilities – All personnel, whether employed, contracted or affiliated with Cleveland Clinic, including all physicians, health care providers and students of Cleveland Clinic. Cleveland Clinic facilities are defined as all facilities and respective campuses and regional hospitals, whether owned, leased, rented or controlled by Cleveland Clinic.

Supplier – Manufacturers, suppliers, distributors, or providers of products, equipment or services, whether medical or non-medical.

Vendor Representative(s) – Any individual who visits Cleveland Clinic for the purpose of soliciting, marketing or distributing information regarding the use of products or services.

Non-Employee: Individuals who need access to Cleveland Clinic property who do not receive a pay check with a Cleveland Clinic logo on it. Examples are students, contractors, observers, etc.

Remote Access Users: An individual who requires access to Cleveland Clinic systems in order to deliver on scope of work or service level agreement.

Department Representative: The Cleveland Clinic employee who is authorizing the nonemployee to be on Cleveland Clinic property. The Department Representative is responsible for the non-employee while they are on Cleveland Clinic property.

Patient Care Area: An area that an individual will or may come into contact and/or in the same vicinity with patients of the Cleveland Clinic. Tuberculosis (TB) tests are required for all non-employee whose primary work location is in a patient care area.

Weapon: Any device that could be carried, possessed or used for the purpose of inflicting physical harm.

Occurrence: A visit to Cleveland Clinic property, regardless of the number of hours onsite.

Instructions

All non-employees on Cleveland Clinic property must be on boarded/badged through an approved method.

Please use the matrix below to determine if a supplier representative shall be on boarded through the non-employee (i.e. SilkRoad) or Vendor (i.e. Vendormate) process. See below for potential exceptions.

	Non-Employee	Vendor	
System Utilized	SilkRoad	Vendormate/GHX	
Role	Contractors, construction workers, observers, couriers, visiting researchers, students, volunteers	Any individual who visits Cleveland Clinic for the purpose of soliciting, marketing or distributing information regarding the use of products or services.	
Location	In clinical/non-clinical areas, patient facing, or a patient care facility (see definition above)	In non-clinical areas (meeting with Supply Chain, physician offices, repairing equipment, etc.) or clinical areas for product trials	
Compliance Requirements	Tuberculosis (TB) test, flu shot (seasonally), online compliance courses (i.e MyLearning) (annually), and background check		
Background Test Facilitator	Cleveland Clinic background check	GHX background check	
Badge Type	Hard badge	Sticky badge	
Badge Expiration	One year, unless otherwise approved	A new badge must be printed for each visit upon check in. Sign out mandatory.	
Initiate Process	Cleveland Clinic personnel submits Onboarding Request Form or Event Coordinator initiates	Sales representative registers in credentialing software (i.e. Vendormate/GHX)	
Approval	Cleveland Clinic personnel authorizes non-employee prior to start date	Scheduled appointment with Cleveland Clinic personnel required for every visit	

Orientations are the responsibility of the department representative.

If you have any questions, please reach out to onboarding support at nonemployeeonboarding@ccf.org or by phone at 216-448-0082.

Potential Exceptions to the onboarding/badging process:

• Supplier representatives on site for a 'vendor fair'

- Supplier representatives meeting with Executive level leadership
- Supplier representatives demoing a product not in a patient care area
- Supplier representatives participating in a Request for Information (RFI) or Request for Proposal (RFP)

Non-employees without a badge must be escorted by personnel within the department hosting the experience and sign a confidentiality agreement. In order to obtain a confidentiality agreement please reach out to your Supply Chain representative. On boarded / badged construction workers are permitted to be on the job site unescorted due to the nature of work performed. Otherwise, local non-badged, non-employees must coordinate with local Facility Manager prior to coming onsite.

Onboarding Program for Non-Employees

Protective Services manages the non-employee onboarding process and maintains all compliance documentation. Each non-employee is required to complete the onboarding process prior to arrival on Cleveland Clinic property and prior to badge expiration date. All users must adhere to the Security Administrative Services guidelines regarding program access.

All non-employees are responsible for completing the tasks that have been assigned to them as outlined in the Conditions of Use Violations of the Conditions of Use will be investigated.

Protective Services reserves the right to audit any information submitted to the program with academic institutions or external entities. Upon request of a document, it must be provided to Security Administrative Services within 24 hours.

Data entered into the program is protected by the software provider. The Cleveland Clinic protects the confidentiality, integrity, and availability of all data that it receives, maintains, or transmits.

Security Administrative Services has ultimate program oversight and can inactivate the onboarding process.

Security Administrative Services will report all SOP violations to the department representative/sponsor and the contracted leadership.

Non-Employee Badging

All non-employee representatives who will be on Cleveland Clinic property in a patient or clinical area, must obtain, display, and renew valid identification badges through the ID Badge Department within Protective Services. The onboarding requirements will be completed prior to receiving an active badge and include the following, or variations of the following:

- 1. Submit basic information such as name, email, Social Security Number (SSN), Date of Birth (DOB), address used to populate the badge system
- 2. Complete a background release form

- 3. Complete a confidentiality agreement
- 4. Acknowledge Conditions of Use
- 5. Submit verification of negative TB test if necessary
- 6. Read and acknowledge enterprise-wide policies
- 7. Complete online compliance courses (i.e. MyLearning)
- 8. Register their vehicle for parking
- 9. Flu shot compliance
- 10. Department-specific requirements

Vendor Requirements are subject to change at any time based on needs of stakeholders, departments, the Cleveland Clinic enterprise, or government regulations. All Cleveland Clinic employees who have oversight of non-employees, contracted companies, affiliated colleges and universities, will adhere to the onboarding process Cleveland Clinic requires as outlined within this standard operating procedure.

Non-Employee Departure

All Cleveland Clinic badge holders must return to the Badging Office upon departure.

It is the department representative's responsibility to communicate to Security Administrative Services when the non-employee no longer requires access to Cleveland Clinic property.

Individuals found to be non-compliant are subject to removal from the property.

Onboarding Program for Vendor Representatives

Protective Services manages the supplier/vendor representative's onboarding process and maintains all compliance documentation. Each representative is required to complete the onboarding process prior to arrival on Cleveland Clinic property.

Security Administrative Services has ultimate program oversight and can inactivate the onboarding process.

Security Administrative Services will report all SOP violations to the department representative/sponsor and the contracted leadership.

Vendor Representative Badging

All Vendor Representatives determined who will be on Cleveland Clinic property in a patient or clinical area, must obtain, display, and renew valid identification through Protective Services. The onboarding requirements will be completed prior to entering a patient area and include the following, or variations of the following:

- 1. Submit basic information such as name, email, Social Security Number (SSN), Date of Birth (DOB) to the vendor credentialing software (i.e. GHX/Vendormate)
- 2. Complete a background release form
- 3. Complete a confidentiality agreement
- 4. Acknowledge Conditions of Use
- 5. Submit verification of negative TB test if necessary
- 6. Read and acknowledge enterprise-wide policies
- 7. Complete online compliance courses (i.e. MyLearning)
- 8. Flu shot compliance
- 9. Department-specific requirements (signing in and out of area)

Requirements are subject to change at any time based on needs of stakeholders, departments, the Cleveland Clinic enterprise, or government regulations. All Cleveland Clinic employees who have oversight of representatives, contracted companies, will adhere to the onboarding process Cleveland Clinic requires as outlined within this standard operating procedure.

Visitations:

- A Vendor Representative must have a badge showing on their person at all times on Cleveland Clinic property. If a Vendor Representative is on Cleveland Clinic property and does not have a badge, they are required to sign a Non-Disclosure Agreement (NDA) and be accompanied by a Cleveland Clinic employee at all times.
 - o If a Vendor Representative is seen without a badge on while in a patient care area, caregivers should ask them to leave. If they refuse, call Protective Services immediately.
- Vendor Representatives are required to have an appointment, sign-in and sign-out via credentialing software (i.e. GHX/Vendormate) for all visits. Visitation hours must be consistent with normal hours of operation for Cleveland Clinic unless requested by department employee. Non-contracted vendors require Physician authorization prior to entering into any clinical space.
- Vendor Representative may be present in a patient care area when needed for treatment, payment, or health care operation purposes, for example, providing the support necessary for a physician to utilize the product or device safely or education/training.
 - A HIPAA authorization is required when the Vendor Representative's presence in the patient care area is not for treatment, payment, or health care operations purposes. (See <u>HIPAA Authorization Policy No. 2066</u> and <u>HIPAA Privacy</u> <u>Glossary Policy</u> for additional information.)

- When such an authorization is required, prior to the admission of the Vendor Representative into the patient care area, a clinical caregiver must verify that the patient's authorization concerning the Vendor Representative's presence has been obtained and documented in the patient's medical record.
- Vendor Representatives are not permitted to move freely about in areas not pertaining to their specific visit, including but not limited to staff break rooms, other operating suites or physician offices. Unannounced visits and soliciting of promotional activities by Vendor Representatives are strictly prohibited.
 - o If a Vendor Representative is seen in an unauthorized area, call Protective Services immediately.
- When in any clinical space, under no circumstances will a Vendor Representative be permitted to:
 - o Participate in hands-on delivery of patient care (e.g. scrub)
 - o Provide initial training of equipment and/or supplies during a procedure
 - Independently hand up implants to the field. Implants must be verified by
 Cleveland Clinic caregivers following the Implant Verification process as outlined
 in the 'Universal Protocol Safety Checklist Policy and Florida Universal Protocol
 - Safety Checklist Policy prior to implantation.'
- While visiting Cleveland Clinic's main campus, Vendor Representatives are required to wear orange scrubs and a red bouffant while in operating rooms (ORs) and procedural areas, which includes during all participation or observation of a clinical procedure.
 - The scrub and bouffant colors are specific to Vendor Representatives and are designed to ensure easy identification.
 - o If additional spaces require a bouffant, Vendor Representatives must wear a red bouffant cap.
 - When leaving the surgical or procedure rooms, Vendor Representatives must remove their red bouffant and cover their scrubs with a white, buttoned lab coat while inside the hospital. Red bouffant caps should not be worn more than once.
 - This attire cannot be worn when traveling to and from work. Vendor Representatives must completely change out of their scrubs with or without a lab coat before leaving the premises.
 - o If Vendor Representatives do not comply with these guidelines, they may risk loss of privileges of the clinical areas and all other Cleveland Clinic facilities.
 - If a Vendor Representative is seen without a badge or red bouffant, call Protective Services Immediately
- For all other Cleveland Clinic facilities, the specific location will provide the Vendor Representative with their scrubs and a red disposable bouffant. The red disposable bouffant must be worn when entering operating rooms (ORs) and procedural rooms, which includes during all participation or observation of a clinical procedure.

- The bouffant color is specific to Vendor Representatives and designed to ensure easy identification.
- o If additional spaces require a bouffant, Vendor Representatives must wear a red bouffant cap.
- When leaving the surgical or procedure rooms, Vendor Representatives must remove their red bouffant. Red bouffant caps should not be worn more than once.
- This attire cannot be worn when traveling to and from work. Vendor Representatives must completely change out of their scrubs with or without a lab coat before leaving the premises.
- o If Vendor Representatives do not comply with these guidelines, they may risk loss of privileges of the clinical areas and all other Cleveland Clinic facilities.
- o If a Vendor Representative is seen without a badge or red bouffant, call Protective Services immediately.

Contracting and Sales:

- Vendor representatives may only discuss price, or negotiation of price, and/or contract with Supply Chain Support Services. Under no circumstances shall the Vendor Representative solicit new products and/or technology improvements, services, or contracts in hospital areas other than with Supply Chain Support Services.
- Cleveland Clinic reserves the right to refuse to pay for any product or service not authorized by Supply Chain Management or the specific department. Contracts must be approved by Supply Chain Management prior to execution. A contract signed by anyone other than an officer, or their delegate, of the respective corporation is not valid.
- Vendor Representatives are not permitted to provide anything of value to a Cleveland Clinic employee that could influence or be perceived as influencing the judgment of the employee in the execution of his/her duties. To this end, no gifts whatsoever, including meals, shall be requested or accepted from vendors. Vendor Representatives and Cleveland Clinic employees are asked to report any violations of this procedure to the

Law Department. For more information please reference the 'Financial Interest Disclosure Procedure.

• If Cleveland Clinic personnel are employed by vendors as an additional employer, that employee is prohibited from engaging Cleveland Clinic on behalf of the vendor. This includes, but is not limited to, activity on vendors' behalf such as sales calls, emails, visits and patient care.

General Requirements:

- Vendors are not permitted to use Cleveland Clinic phones, computers or other equipment for supplier's business or personal use.
- Vendor may not distribute or post any type of brochure, advertisements, pens, cups or similar promotional or marketing materials in the OR and/or associated areas or to any personnel.

- Vendor Representatives are not permitted to increase inventory levels in storerooms and/or clinical areas.
- Vendor Representatives are not permitted to bring into procedural area, OR, clinical area, or patient care areas any device that has the capability to record or transmit audio and/or video images, including photography.
- Vendor Representatives Expectations while on Cleveland Clinic property:
 - All items brought in by a Vendor Representative must be off the floor (bottom shelf 8 inches off the floor with solid bottom or cover). No items can be within 18 inches of a sprinkler head. Items are never to be placed in front of a fire extinguisher, fire pull stations, emergency gas panels, electrical panels, or any other emergency equipment.
 - Vendor Representatives are not permitted to store personal items (bags, coats, etc.)
 in patient care areas
 - No food or drink is permitted in patient care areas at all times o All sterilized instruments must be returned to Sterile Processing (SPD) and stored in temperature/humidity-monitored rooms
 - All vendor-owned bins must be cleaned monthly and as needed. Mark the bins as 'for clean supplies only' o Vendors Representatives must remove all external shipping containers and corrugated boxes they bring into Cleveland Clinic facilities

Equipment/ Device/ Implant Set:

- All equipment/device/implant sets to be used by Vendor Representatives must be delivered at least 24 hours before a scheduled procedure to allow for inventory, sterilization, and/or biomedical safety evaluation in accordance with Cleveland Clinic's policies. Cleveland Clinic will not pay for equipment until the day of its use regardless of when it is brought in.
- Cleveland Clinic will not pay for any implant that has not been approved by the Supply Chain Sourcing team or a Cleveland Clinic standard product.
- All new products are subject to review by Supply Chain. A formal process has been established for the documentation of product evaluations. For details on this process refer to the Operating Room New Product Committee SOP. Supply Chain and Support Services will provide assistance with the required documents.
- All equipment/device/implant sets must contain a complete inventory checklist plus
 written cleaning and sterilization instructions.

 This includes consigned and loaner
 instrumentation sets.
 - The inventory list for each kit must be made available in hard copy and electronically in Excel format and be provided to the corresponding department.
 - The inventory list must also be reconciled with the vendor and Cleveland Clinic personnel.

- All equipment and instrument trays must be removed within 48 hours of use.
- Upon completion of the surgical procedure, a complete inventory of any equipment, device, implant sets, or any other products brought into or used must be completed by the clinical staff.
- All instruments and related equipment used in the clinical area must be properly
 decontaminated prior to removal from Cleveland Clinic in accordance with Cleveland
 Clinic's policies and procedures.
- All staff training for new equipment, instrumentation or surgical instruments must be coordinated through Cleveland Clinic's clinical leadership at least one week prior to the scheduled surgical procedure.
- Under no circumstances will a Vendor Representative be permitted to:
 - Participate in hands-on delivery of patient care (e.g. scrub) Provide initial training of equipment and/or supplies during a procedure Independently hand up implants to the field. Implants must be verified by Cleveland Clinic caregivers following the Implant Verification process as outlined in the 'Universal Protocol Safety Checklist Policy and Florida Universal Protocol
 - Safety Checklist Policy prior to implantation'

Pharmaceutical Representatives:

For information surrounding pharmaceutical vendor representatives please refer to the below policies:

- <u>Pharmaceutical Sales Representatives Policy</u> and <u>Florida Pharmaceutical Sales</u> <u>Representatives Policy</u>
- <u>Cleveland Clinic Medical Staff P&T Committee Functions Policy</u> and <u>Florida Medical Staff P&T Committee Formulary System Policy</u>
- Requests for Formulary Changes Through the Cleveland Clinic United States Medical Staff P&T Committee Policy and Requests for Formulary Changes Through the Cleveland Clinic United States Medical Staff P&T Committee Policy

Supplier Non-Compliance:

- 1. Vendor Representatives who fail to comply with Cleveland Clinic policies will be subject to disciplinary action up to and including permanent loss of business privileges.
- 2. Continuous infractions or repeated violations to this standard operating procedure by Vendor Representatives may result in suspension, a request to replace company representatives, and possible loss of business privileges at Cleveland Clinic.

- 3. Violations committed by any one Vendor Representative of a given company may result in disciplinary action against any or all representatives of that company.
- 4. Disciplinary action may vary depending upon the nature of the infraction and the circumstances surrounding the offense. Supply Chain & Support Services reserves the right to determine the severity of the infraction and will use its discretion when assessing and determining the proper course of disciplinary action. Consequences may vary depending on the severity of the infraction. For a full list of infractions, please refer to the Vendor Violation Reporting and Corrective Action Directive.
- 5. Supply Chain and Support Services will notify the Vendor Representative of the violation, the determined level of infraction, and the planned course of disciplinary action.
- 6. Duration of restriction of all activity and service calls may be 3 months, 6 months, one year, or permanent depending on extent of the infraction. Certain situations may require deviation from the guidelines outlined in this SOP. Vendor Representatives can be banned from Cleveland Clinic permanently regardless of Vendor Representative's employer.
- 7. Cleveland Clinic reserves the right to discipline, demote or discharge at will and without regard to the foregoing criteria and procedures.

Resources

Vendor Handbook

Link to *Authorization to Disclose Health Information*: http://my.clevelandclinic.org/ccf/media/Files/Patients/records-release-form.pdf

Regulatory Requirements/References

Joint Commission ORC.2901.01; EC.02.01.01 HR.01.02.05 HR.01.04.01 <u>Identification Badges Policy</u> <u>Weapons and</u> <u>Contraband Policy</u>

Oversight and Responsibility

Supply Chain & Support Services and Protective Services are responsible to review, revise, update, and operationalize this standard operating procedure to maintain compliance with regulatory or other requirements. It is the responsibility of each hospital, institute, department and discipline to implement the SOP and to draft and operationalize related procedures to the SOP if applicable.

Cleveland Clinic personnel reserve the right to refuse entry to Cleveland Clinic property based on results of the background check. An offer of a non-employee experience is subject to be rescinded at any time. Non-compliance to any element of the onboarding process will result in denial of badging and entry into Cleveland Clinic facilities.

Weapons are not permitted on Cleveland Clinic premises, at enterprise sponsored functions, while conducting organization business off-premises or in Cleveland Clinicowned or leased vehicles. Cleveland Clinic premises include all enterprise-owned or leased buildings and surrounding areas such as parking lots, sidewalks and driveways.

Individuals in violation of the Weapons and Contraband SOP will immediately be removed from Cleveland Clinic property, their management team will be notified, and they could be subject to criminal prosecution.